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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|---|---------------------|------------------|
| 10/712,399 | 11/14/2003 | Kevin M. Moore | 1533.3500003 | 6849 |
| 26111 | 7590 | 09/07/2006 | | EXAMINER |
| | | STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005 | | OH, TAYLOR V |
| | | | ART UNIT | PAPER NUMBER |
| | | | | 1625 |

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/712,399 | MOORE ET AL. | |
| | Examiner | Art Unit | |
| | Taylor Victor Oh | 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 June 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4-10 and 13-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-10 and 13-66 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11/14/03 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

Applicant's arguments with respect to claims 1-2, 4-10, and 13-66 have been considered but are moot in view of the new ground(s) of rejection.

The Status of Claims

Claims 1-2, 4-10, and 13-66 are pending.

Claims 1-2, 4-10, and 13-66 have been rejected.

DETAILED ACTION

Priority

1. It is noted that this application is a CIP of 09/955,672 filed on 09/19/2001(US 6,849,748), which claims benefit of 60/244,962 (11/01/2000).

Drawings

2. The drawing filed on 11/14/03 is accepted by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2,13-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for acidic exchange resins, acidic zeolite powder as a solid acid catalyst does not reasonably provide enablement for all kinds of solid acid

catalysts known in the art. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all kinds of solid acid catalysts unrelated to the claimed invention commensurate in scope with these claims.

Furthermore, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation, citing *Ex Parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The Nature of the Invention

The nature of the invention in claim 1 is the process for preparing an anhydrosugar alcohol by heating a sugar alcohol, and dehydrating the starting material in the presence of a solid acid catalyst.

The State of the Prior Art

The states of the prior art are described as followed:

Hartmann (U.S. 3,454,603) discloses a process of preparing 1,4-3,6-dianhydroglucitol by heating hexitols, such as 1,4 D,L-allitan ,D-sorbitol, D-mannitol ,1,4 D,L-dulcitan , in the presence of an acid dehydration catalyst , such as sulfuric acid , p-toluenesulfonic acid at a temperature of from 110 to 185⁰ C. , and then distilling the reaction mixture to recover dianhydrohexitols ,such as D-isosorbide, D-isomannide at low pressures of from 0.03 to 100 mmHg. In addition, the products may be further purified by recrystallization .

Feldmann et al (U.S. 4,564,692) teaches a process of purifying the anhydro sugar alcohols by crystallization from a concentrated solution in the absence of organic crystallization solvents . Furthermore, all aqueous anhydro sugar alcohol solutions with a suitable concentration have been obtained from acid-catalyzed dehydration of hexitols with strongly acidic cationic exchange resins; the crystalline anhydro sugar alcohols can be separated from the mixture by centrifugation or filtration. In addition, if the heavy liquors contain two or more different anhydro sugar alcohols, it is possible to use fractional crystallization in succession in order to produce the pure crystalline form ; also, it is advisable to conduct the crystallization process at a temperature of from 20 to 65⁰ C.

Brinegar et al (WO 00/14081) teaches the followings:

The process is directed toward the production of anhydrosugar alcohols and generally includes the steps of introducing at least one sugar alcohol or monoanhydrosugar alcohol into a reaction vessel; dehydrating the sugar alcohol or monoanhydrosugar alcohol in the presence of an acid catalyst and a solvent to form a reaction product which is at least partly soluble in the solvent; removing water from the reaction vessel; removing solvent comprising the dissolved reaction product from the reaction vessel; separating the reaction product from the removed solvent; and recycling the solvent into the reaction vessel. Optionally, the process may further include an additional purification step. Further, the process may be continuous such that the steps of introducing in the starting materials, removing water, removing solvent comprising the dissolved reaction product and recycling the solvent after separation from the reaction product occur simultaneously.

As the prior art have been discussed in the above, there is no conclusive data that all the kinds of solid acid catalysts would be required to produce the final desired product for the process.

The predictability or lack thereof in the art

In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that any solid acid catalyst would not work on the claimed process in the same way as those catalysts such as acidic exchange resins, acidic zeolite powder disclosed in the specification.

According to T.P.Hilditch, the author of the "Catalytic Processes in Applied Chemistry" (see pages Xiii-XV, 1929), there is a definitive reason for an unpredictable aspect of the catalysts in the art of organic chemistry. T.P.Hilditch expressly teaches that any catalyst would not work for any kind of the reaction process; for example, the specific catalysts such as mineral acids, acetic anhydride, sulfuric acid, calcium chloride, and etc can be used for the esterification; on the other hand, this same kind of catalyst will not apply to the other types of the reaction process in the followings: the chlorination of organic compounds, the oxidation of organic compounds, the process for rubber accelerators, the hydrogenation or the dehydrogenation processes, ammonia synthesis, ammonia oxidation, sulfuric acid manufacture, and etc. (see pages Xiii-XV).

Furthermore, the specification of the claimed invention does support the very idea of the unpredictable aspect of the catalysts by disclosing the following specific, workable catalyst for the process, not all kind of the catalyst known in the art: acidic exchange resins, acidic zeolite powder.

Moreover, the case law advocates that the catalyst compositions represent an unpredictable aspect in the art of organic chemistry. See Ex parte Sizto, 9 USPQ2d 2081 (Bd. Of App. And Inter. March 1988). Therefore, the use of a generic phrase "a catalyst" can not ensure to form the desired claimed product in a good yield.

The amount of direction or guidance present

The direction present in the instant specification is that not any solid acid catalyst can be led to the formation of the desired product. According to the specification, it is silent as to how any solid acid catalyst can be led to the formation of the desired product and fails to provide guidance as to whether any catalyst is sufficient enough to allow to form the desired product in sufficient quantities; the specification fails to provide a correlation between the claimed process of the invention and the functional language of any solid acid catalyst .

The presence or absence of working examples

There are only 9 working examples using the same acidic ion exchange resin or a sulfated zirconia pellet for producing the desired compound in the specification. This can not be the representatives for all the solid acid catalysts which would work for the claimed process. Thus, the specification fails to provide working examples as to how the other types of solid acid catalysts can be resulted in the claimed products, i.e. again, there is no correlation between the functional language of any solid acid catalyst and the desired final product.

The breadth of the claims

The breadth of the claims is that any catalyst would work on the claimed process in the same way as those disclosed solid acid catalyst without considering the affect or impact of the different catalysts on the starting compound , thereby affecting the yield of the desired final product.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine which one of the solid acid catalysts would be capable of forming the desired product and would furthermore then have to determine which one of the catalysts would not be resulted in the claimed desired compounds in a sufficient quantity.

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which solid acid catalyst can be employed to produce the desired claimed compound encompassed in the instant claims, with no assurance of success.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-10, and 13-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartmann (U.S. 3,454,603) in view of Feldmann et al (U.S. 4,564,692) and Brinegar et al (WO 00/14081).

Hartmann discloses a process of preparing 1,4-3,6-dianhydroglucitol by heating hexitols, such as 1,4 D,L-allitan ,D-sorbitol, D-mannitol ,1,4 D,L-dulcitan , in the presence of an acid dehydration catalyst , such as sulfuric acid , p-toluenesulfonic acid (see col. 2, lines 25-40) at a temperature of from 110 to 185⁰ C. (see col. 2, lines 49-51), and then distilling the reaction mixture to recover dianhydrohexitols ,such as D-isosorbide, D-isomannide (see col. 1 ,lines 29-30) at low pressures of from 0.03 to 100 mmHg (see col. 2, lines 56-61). In addition, the products may be further purified by recrystallization (see col. 2, lines 69-71).

The instant invention differs from Hartmann in that melt crystallizing , filtering , and centrifuging the anhydro sugar alcohol are unspecified; the acidic ion exchange resin is added in an amount of from 0.01 to 0.15 gram equivalents to sugar alcohol; the acid catalyst contains a zeolite powder selected from CBV 3024, CBV 5534G, AG50W-X12; the use of the film evaporator is not disclosed.

Feldmann et al teaches a process of purifying the anhydro sugar alcohols by crystallization from a concentrated solution (see col. 1 ,lines 6-10) in the absence of organic crystallization solvents (see col. 1 ,lines 65-67). Furthermore, all aqueous anhydro sugar alcohol solutions with a suitable concentration have been obtained from acid-catalyzed dehydration of hexitols (see col. 4 ,lines 9-11) with strongly acidic cationic exchange resins (see col. 4 ,lines 60-61); the crystalline anhydro sugar alcohols can be separated from the mixture by centrifugation or filtration (see col. 4 ,lines 25-27). In addition, if the heavy liquors contain two or more different anhydro sugar alcohols, it is possible to use fractional crystallization in succession in order to produce the pure crystalline form (see col. 4 ,lines 35-39); also, it is advisable to conduct the crystallization process at a temperature of from 20 to 65⁰ C. (see col. 3 ,lines 18-19).

Furthermore, Brinegar et al teaches the followings:

The process is directed toward the production of anhydrosugar alcohols and generally includes the steps of introducing at least one sugar alcohol or monoanhydrosugar alcohol into a reaction vessel; dehydrating the sugar alcohol or monoanhydrosugar alcohol in the presence of an acid catalyst and a solvent to

form a reaction product which is at least partly soluble in the solvent; removing water from the reaction vessel; removing solvent comprising the dissolved reaction product from the reaction vessel; separating the reaction product from the removed solvent; and recycling the solvent into the reaction vessel. Optionally, the process may further include an additional purification step. Further, the process may be continuous such that the steps of introducing in the starting materials, removing water, removing solvent comprising the dissolved reaction product and recycling the solvent after separation from the reaction product occur simultaneously.

Typical sugar alcohols, in particular pentites and hexites, are suitable for use in the process as starting materials. The starting materials may be sugar alcohols, monoanhydrosugar alcohols, or a mixture thereof. In particular, preferred starting materials include arabinitol, ribitol, D-glucitol (also known as D-sorbitol or sorbitol), D-mannitol (mannitol), galactitol and iditol. The use of sorbitol is particularly desirable because sorbitol is readily available and can be obtained on a large industrial scale by the reduction of glucose with hydrogen, as known to one of ordinary skill in the art.

The catalysts used to facilitate the dehydration reaction are acid catalysts. Several types of acid catalysts may be used, each having specific advantages and disadvantages. One class of acid catalyst that may be used includes soluble acids. Examples of such acid catalysts include sulfuric acid, phosphoric acid, p-toluene sulfonic acid, methanesulfonic acid and the like. Sulfuric acid is a preferred catalyst from this class. Alternatively, acid anion exchange resins may also be used, such as sulfonated polystyrenes. A preferred acid anion exchange resin is AG50W-X12 from BioRad. Inorganic ion exchange materials may also be used, such as acidic zeolites. In particular, H-beta zeolite from Degussa may be used in the process disclosed herein.

(see from page 5 ,line 24 to page 6 , line 27).

Furthermore, Brinegar et al has indicated that the reaction product is separated from theremoved organic solvent by recrystallization and evaporation (see page 23, lines 14-15).

Concerning the addition of the amount of from 0.01 to 0.15 gram equivalents of resin to sugar alcohol, the limitation of a process with respect to ranges of pH, ratio and period does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. Ratio is well understood by those of ordinary skill in the art to be result-effective variables, especially when attempting to control selectivity of a chemical process in the absence of an unexpected result.

With respect to the use of the acid catalyst containing the zeolite power selected from CBV 3024, CBV 5534G, AG50W-X12, the prior art references are silent. However, it is well-known in the art that AG50W-X12 acidic catalyst can be used with an advantage of little or no residue in producing anhydro sugar alcohols as shown in Brinegar et al (see page 7 ,lines 5-6). Therefore, it would have been obvious to the skilled artisan in the art to be motivated to use the Brinegar et al AG50W-X12 as a substitute. This is because the skilled artisan in the art would expect to improve on the purity of the desired compound by using the AG50W-X12 catalyst in the process.

Hartmann does disclose the process of preparing 1,4-3,6-dianhydroglucitol by heating hexitols in the presence of sulfuric acid at a temperature of from 110 to 185° C., and then distilling the reaction mixture to recover dianhydrohexitols at low pressures, furthermore, the products may be purified by recrystallization. Also, Feldmann et al expressly teaches the process of purifying the anhydro sugar alcohols obtained from acid-catalyzed dehydration of hexitols by crystallization from a concentrated solution in the absence of organic crystallization solvents; moreover, when sugar alcohols are dehydrated, the reaction mixtures contain various impurities detrimental to the production of polyesters (see col. 1 ,lines 23-30). Furthermore, Brinegar et al has offered guidance that AG50W-X12 acidic catalyst can be used with an advantage of little or no residue in producing anhydro sugar alcohols (see page 7 ,lines 5-6) as a substitute..

Therefore, it would have been obvious to the skilled artisan in the art to be motivated to incorporate the Feldmann et al crystallization technique into Hartmann along with Brinegar's et al AG50W-X12 acidic resin catalyst in order to further purify the desired product suitable for producing polyesters. This is because the skilled artisan in the art would expect such a combination to be feasible and to improve on the purity of the desired compound by applying the Feldmann et al crystallization technique to the Hartmann process as shown in the Brinegar et al prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Mary W. H.
primary Examiner
9/14/06.*